

AD _____

Award Number: DAMD17-99-1-9330

TITLE: Radiologist Evaluation of DEI Breast Specimen Imaging

PRINCIPAL INVESTIGATOR: Etta D. Pisano, M.D.

CONTRACTING ORGANIZATION: University of North Carolina
Chapel Hill, North Carolina 27599-7510

REPORT DATE: July 2001

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are
those of the author(s) and should not be construed as an official
Department of the Army position, policy or decision unless so
designated by other documentation.

20020717 096

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED	
	July 2001	Annual (1 Jul 00 - 30 Jun 01)	
4. TITLE AND SUBTITLE Radiologist Evaluation of DEI Breast Specimen Imaging			5. FUNDING NUMBERS DAMD17-99-1-9330
6. AUTHOR(S) Etta D. Pisano, M.D.			
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of North Carolina Chapel Hill, North Carolina 27599-7510 E-Mail: etpisano@med.unc.edu			8. PERFORMING ORGANIZATION REPORT NUMBER
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSORING / MONITORING AGENCY REPORT NUMBER
11. SUPPLEMENTARY NOTES			
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited			12b. DISTRIBUTION CODE
13. ABSTRACT (Maximum 200 Words) The purpose of this study is to determine which physical operating characteristics for obtaining the DEI images to provide the optimum image for breast cancer imaging. This determination will be based on expert observer studies. The results will then be used as the design specifications for a compact source. We have decided to use breast imaging phantoms instead of breast tissue samples based on the preliminary study performed on the breast tissue samples. Two phantoms are being used. The images for the phantoms have been acquired and registered. Other image processes are in progress and reader study is being scheduled.			
14. SUBJECT TERMS Breast Cancer			15. NUMBER OF PAGES 9
			16. PRICE CODE
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

 Where copyrighted material is quoted, permission has been obtained to use such material.

 Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

 Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

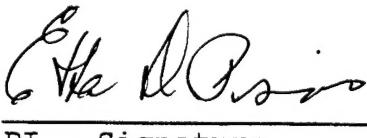
 In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and use of Laboratory Animals of the Institute of Laboratory Resources, national Research Council (NIH Publication No. 86-23, Revised 1985).

✓ For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

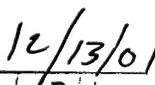
 In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

 In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

 In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.



PI - Signature



Date

Table of Contents

	Page
Foreword	3
Introduction	5
Body	5
Key Research Accomplishments	8
Reportable Outcomes	8
Conclusions	8
References	8
Appendices	8

INTRODUCTION (from original grant)

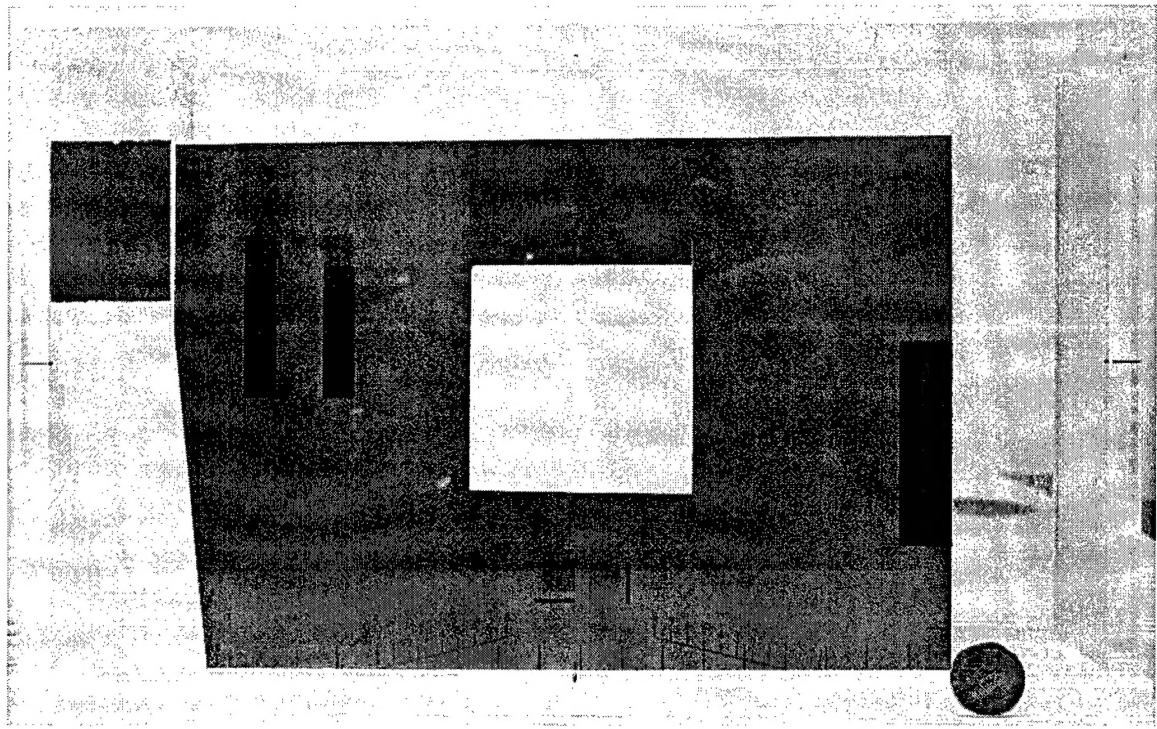
The purpose of this study is to determine which physical operating characteristics for obtaining the DEI images to provide the optimum image for breast cancer imaging. This determination will be based on expert observer studies. The results will then be used as the design specifications for a compact source. The Hypothesis is that there is a set of operating characteristics that will provide optimal visibility of the mammographic features of breast cancer. The specific aims of this proposal are to determine the physical characteristics of the acquisition of DEI images for breast imaging. There are numerous parameter values for collection of DEI images and design specifications of a compact source for breast imaging depend upon what these values are. An observer study is proposed which will allow expert radiologists to score DEI images obtained with different acquisition parameter values. From this study, we can determine the optimal design specifications for a clinically useful breast imaging system.

BODY

Numerous images of tissue samples and phantoms have been taken using the DEI technique, but the optimal imaging parameters have not been determined. Determining these parameters is a necessary step in the characterization of DEI and the future development of a clinically based system. The imaging parameters being studied are: the imaging energy, the crystal reflection, and the location on the rocking curve. Data obtained from this experiment will be used to determine the optimal imaging parameters for subsequent DEI experiments.

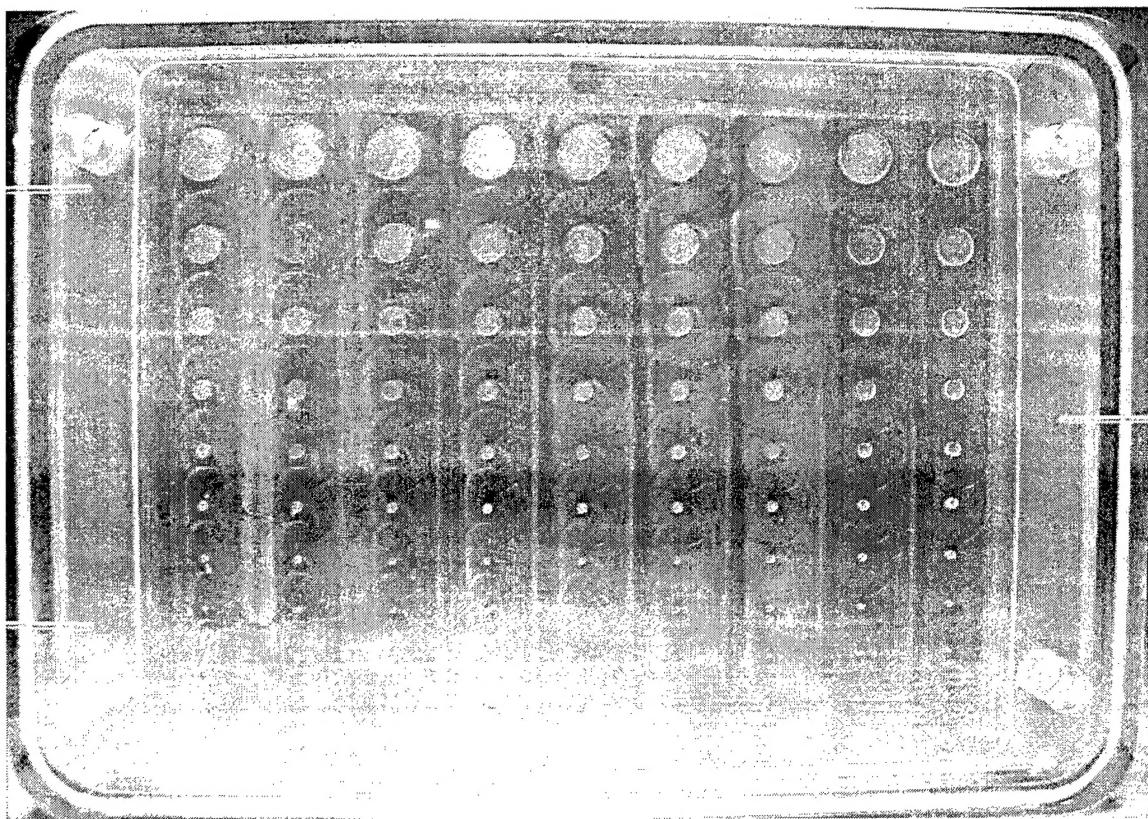
The first two sections of this project were completed using breast tissue samples. These images were processed and prepared for a reader study to determine the optimal parameters for DEI. However, further analysis of these images revealed that breast tissue specimens did not provide the data necessary to fully characterize the effect of the parameters on image quality. We learned from this initial experiment that the information needed could be more accurately quantified using breast imaging phantoms. Two phantoms were selected and for imaging at the National Synchrotron Light Source (NSLS).

The phantoms being used for the experiment are the International Digital Mammography Development Group Phantom (IDMDG) phantom and the Contrast-Detail (CD) phantom. The level of detail in these phantoms make them well suited for DEI imaging and provide the statistical data necessary to determine the optimal imaging parameters. The IDMDG phantom contains several regions of interest that will help to demonstrate the resolution of DEI. For example, one of the regions includes a series of 14 clusters each containing 6 specs. Close inspection of the specs demonstrates they are actually stars. These details are difficult to observe in conventional radiography, but it is believed that they will be clearly seen using DEI. These regions simulate calcifications and will provide valuable data as to the optimal configuration for their visualization.



IDMDG Phantom

The CD Phantom has a 9 x 10 grid of circles that gradually decrease in size and contrast. This phantom contains essentially one region of interest; the reader will state the smallest circle that can be clearly seen. This phantom is well suited for determining the optimal imaging parameters because it is a standardized grid that provides valuable information on both decreasing size and contrast. The CD phantom provides a defined scale for determining the full resolving capability of the modality, a characteristic that available breast tissue samples lack.



CD Phantom

The first step in the experiment was the acquisition of sample images. The experimental specimens were imaged through two distinct mechanisms: standard digital mammography using the UNC Fischer digital mammography system, and diffraction enhanced imaging at the National Synchrotron Light Source (NSLS) at Brookhaven National Labs (BNL).

These steps have been completed for the phantoms, and the reader study is being prepared at this time. The use of phantoms makes it possible for persons other than radiologists to evaluate the images. Given the nature of the experiment, both radiologists and physicists experienced in reading phantoms will be included. Twenty readers, all trained in the interpretation of phantoms through their participation in prior studies, will participate in this study. Readers will be asked to rate the sharpness and diagnostic detail within regions of interest for the experimental versus the control image.

Image processing is a time consuming but key component of the DEI process. The image processing component is almost complete for the phantom images, and a reader study is slated to begin in January 2002. Given the time necessary for each reader to complete the image set, the reader study will take approximately three months to complete.

Once completed, the data from the observer study will be analyzed by Dr. Keith Muller, UNC Department of Biostatistics. This study is critical for further analysis and characterization of Diffraction Enhanced Imaging. Once optimal parameters are

determined, we will be able to further define the physical characteristics of DEI and more importantly its applications to medical imaging.

KEY RESEARCH ACCOMPLISHMENTS

- Imaged four breast tissue samples with DEI at each of the selected acquisition parameters.
- Transferred images from synchrotron facility to UNC.
- Applied image enhancements, cropping and registration to each image.
- Preliminary observer evaluation of images.
- Determined that tissue samples did not provide quantitative data needed to evaluate the acquisition parameters.
- Selected two mammographic phantoms that would provide the quantitative data. Contrast Detail phantom and the International Digital Mammography Development Group phantom. This later phantom was developed specifically for evaluation of digital mammography.
- Acquired DEI images of both phantoms at the selected acquisition parameters.
- Acquired digital images of both phantoms as controls.
- Preparing images for observer study.

REPORTABLE OUTCOMES

Not available at this moment.

CONCLUSIONS

The experiment is currently in progress with an expected completion date of March 2002. Data analysis will proceed immediately following the completion of the project and is scheduled for completion in June 2002.

REFERENCES

APPENDICES

Pisano ED, Johnston RE, Chapman D, Geradts J, Sayers D, Thomlinson W. Diffraction Enhanced Imaging of Human Breast Cancer Specimens: Improved Conspicuity of Lesion Detail with Histologic Correlation. *Radiology Radiology* 2000; 214(3); 895-901.

Chapman D, Thomlinson W, Johnston RE, Washburn D, **Pisano E**, Gmur N, Zhong Z, Menk R, Arfelli F, Sayers D. Diffraction enhanced x-ray imaging. *Phys Med Biol* 1997;42(11):2015-2025.

Johnston RE, Washburn D, **Pisano E**, Burns C, Thomlinson WC, Chapman LD, Arfelli F, Gmur NF, Zhong Z, Sayers D. Mammographic phantom studies with synchrotron radiation. Radiology 1996;200(3):659-63.